

JUN 10 2002

K021 388

**SEAL POLYMER INDUSTRIES SDN. BHD.**

Lot 72706, Jalan lahat, Kawasan Perindustrian Bukit Merah, 31500 Lahat, Perak Malaysia.

Tel: 605-3223 200 Fax: 605- 3222 300

E-mail: spoly@po.jaring.my

**1.0**

**SMDA 510 (K) SUMMARY**

**2.0**

**Submitter**

SEAL POLYMER INDUSTRIES SDN BHD

Lot 72706, Jalan Lahat

Kawasan Perindustrian Bukit Merah

31500 Lahat, Perak, Malaysia

**Tel**

(60 5) 322 3200

**Fax**

(60 5) 322 2300

**Name of Contact Person**

Ms. CHUN CHOOI FONG

**Date of Summary Prepared**

March 27, 2002

**3.0**

**Name of Device**

**Trade Name**

Cashmere Powder Free Latex Examination Gloves

**Common Name**

Exam Glove

**Classification Name**

Patient Examination Glove

**4.0**

**Identification of The Legally Marketed Devices**

Class 1 Polymer Coated Patient Examination Glove 80 LYY, powder free that meets all the requirements of ASTM Standard D3578-00a and FDA requirements.

**5.0**

**Description of The Device**

Class 1 Polymer Coated Patient Examination Glove 80 LYY, powder free that meets all the requirements of ASTM Standard D3578-00a and FDA Water Leak Test.

**6.0**

**The Intended Use of Glove**

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

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**7. Summary of Performance Data :**

Performance data of gloves based on ASTM D3578-00a and FDA 1000 ml watertight test.

TEST	ASTM D3578-00a	CASHMERE POWDER FREE LATEX EXAM GLOVES
1. Watertight (1000 ml)	G I AQL=4.0%	Pass GI AQL=4.0%
2. Length (mm) Size XS S M L XL	Min 230 Min 230 Min 230 Min 230 Min 230	240 mm minimum for all sizes
3. Palm width (mm) Size XS S M L XL	- 80 +/- 10 95 +/- 10 111 +/- 10 -	75 – 78 82 – 88 92 – 98 102 – 108 111 – 115
4. Thickness (mm) (Single Layer)  Finger Palm	Min 0.08 Min 0.08	0.10 minimum 0.10 minimum
5. Physical Properties  <b>Before Aging</b> Tensile Strength (Mpa) Ultimate Elongation (%)  <b>After Aging</b> Tensile Strength (Mpa) Ultimate Elongation (%)	Min 14 Min 650  Min 14 Min 500	25.1 940  18 950
6. Powder Content	-	Below 2 mg / glove
7. Protein Content	-	Below 50 microgram / gram

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8. The performance data of the glove as showed above meet the ASTM D3578-00a Standard and FDA's requirement.  
Powder content is below 2 mg per glove that meets the FDA Requirements.
9. The Biocompatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buehler) test.  
The gloves pass the Biocompatibility Tests.
10. Conclusion

We concluded that the Cashmere Powder Free Latex Examination Gloves meet:

- ASTM D3578-00a Standard
- FDA pinhole requirements
- FDA minimum powder residual content



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Chun Chooi Fong  
Quality Assurance Manager  
Seal Polymer Industrial Sdn. Bhd.  
Lot 72706, Jalan Lahat, Kawasan  
Perindustrian Bukit Merah  
Lahat, Perak,  
MALAYSIA 31500

Re: K021388

Trade/Device Name: Cashmere Non-Sterile, Polymer Coated Powder  
Free Latex Examination Gloves, Contains 50 Micrograms or Less of  
Total Water Extractable Protein Per Gram  
Regulation Number: 880.6250  
Regulation Name: Examination Gloves  
Regulatory Class: I  
Product Code: LYY  
Dated: May 30, 2002  
Received: June 5, 2002

Dear Mr. Fong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

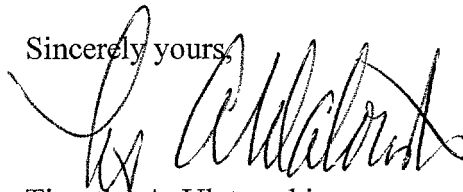
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski", written over the "Sincerely yours," text.

Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

Applicant : Seal Polymer Industries Sdn. Bhd.

510(K) Number: K021388

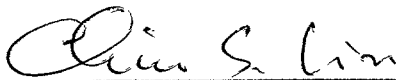
Device Name : Cashmere Powder Free Latex Examination Gloves With Protein Labeling .  
Claim (50 micrograms or less) of Total Water Extractable Protein per gram.

Indication For Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

.....  
Concurrence of CDRH Office of Device Evaluation (ODC)

Prescription Use: ..... OR Over-The-Counter .....  
Per 21 CFR 80.109

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K021388